What is claimed is:

1. A method for making an insulin-containing particulate product, comprising:

contacting an insulin-containing feed solution with a compressed anti-solvent fluid to precipitate insulin-containing particles, the feed solution including the insulin in a cosolvent system including at least a first organic solvent and a second organic solvent that are mutually soluble; and

separating the insulin-containing particles from the anti-solvent fluid.

2. The method of claim 1, wherein insulin is at least about an order of magnitude more soluble in the first organic solvent than in the second organic solvent.

3. The method of claim 1, wherein the first organic solvent and the second organic solvent are present in the solution at a volume ratio of the second organic solvent to the first organic solvent of larger than about 30:70.

4. The method of claim 1, wherein the first organic solvent and the second organic solvent are present in the cosolvent system at a volume ratio of the second organic solvent to the first organic solvent of from about 50:50 to about 90:10.

5. The method of claim 1, wherein the concentration of insulin in the cosolvent system is smaller than about 3 mg of insulin per milliliter of the feed solution.

6. The method of claim 1, wherein the concentration of insulin in the cosolvent system is in a range of from about 0.3 to about 3 mg of insulin per mL of the solution.

7. The method of claim 1, wherein the first organic solvent is selected from the group consisting of DMSO and DMFA.

8. The method of claim 7, wherein the second organic solvent is an alcohol.

9. The method of claim 7, wherein the second organic solvent is a C1-C5 alkanol.

10. The method of claim 1, wherein the compressed anti-solvent , during the contacting, is at a reduced pressure of larger than about 0.8 and a reduced temperature of larger than about 0.95.

11. The method of claim 10, wherein the compressed anti-solvent, during the contacting, is at a reduced pressure of larger than about 0.9.

12. The method of claim 10, wherein the compressed anti-solvent, during the contacting, is in a supercritical state.

13. The method of claim 10, wherein the compressed anti-solvent comprises compressed carbon dioxide.

14. The method of claim 1, wherein the feed solution is substantially free of amphiphillic materials that improve solubility of the insulin in the feed solution through hydrophobic ion pairing with the insulin.

15. The method of claim 1, wherein, during the contacting step, the solution is introduced into the compressed anti-solvent fluid through an opening having a cross-sectional area available for flow that is larger than about 1 square millimeter.

16. The method of claim 15, wherein the solution, when introduced into the compressed anti-solvent fluid has a direction of flow that is at an angle of from about 45° to about 180° relative to the direction of flow of the compressed anti-solvent fluid.

17. The method of claim 1, wherein the cosolvent system includes water, if at all, in an amount of smaller than about 5 weight percent.

18. The method of Claim 1, wherein the cosolvent system is substantially free of water.

19. The method of claim 1, where at least a portion of the insulin in the feed solution is in the form of colloidal particles dispersed in the cosolvent system.

20. A method for making multi-component particles including insulin and a biocompatible polymer for sustained insulin delivery, the method comprising:

contacting a feed solution including both insulin and a biocompatible polymer with a compressed anti-solvent fluid to precipitate multi-component particles including the insulin and the biocompatible polymer, the feed solution including a cosolvent system with at least a first organic solvent and a second organic solvent that are mutually soluble; and

separating the multi-component particles from the anti-solvent fluid.

21. The method of claim 20, wherein the insulin is more soluble in the first organic solvent than is the biocompatible polymer, and the biocompatible polymer is more soluble in the second organic solvent than the insulin.

22. The method of claim 20, wherein the biocompatible polymer is hydrophobic, the first organic solvent being a polar solvent for the insulin and the second organic solvent being a nonpolar solvent for the biocompatible polymer.

23. The method of claim 20, wherein the first organic solvent is substantially miscible with water and the second organic solvent is substantially immiscible with water.

24. The method of claim 20, wherein the second organic solvent comprises at least one of methylene chloride, formaldehyde, dioxolane, chloroform, benzene, ethyl ether, toluene, xylene, 1,3-dioxane and THF.

25. The method of claim 24, wherein the first organic solvent comprises an alcohol.

26. The method of claim 25, wherein the first organic solvent comprises a C_1-C_5 alkanol.

27. The method of claim 26, wherein the first organic solvent comprises at least one of methanol, ethanol and isopropanol.

28. The method of claim 26, wherein the second organic solvent comprises methylene chloride.

29. The method of claim 26, wherein the feed solution further comprises an acid dissolved in the cosolvent system.

30. The method of claim 29, wherein the acid comprises and inorganic acid.

31. The method of claim 29, wherein the acid comprises hydrochloric acid.

32. The method of claim 20, wherein the method comprises, prior to the contacting step, preparing the feed solution, comprising mixing a first solution having the insulin dissolved therein with a second solution having the biocompatible polymer dissolved therein, the first solution including the first organic solvent and the second solution including the second organic solvent.

33. The method of claim 32, wherein during the mixing step, the second solution is added to the first solution.

34. The method of claim 32, wherein the first solution comprises an acid to increase the solubility of the insulin in the first solution.

35. The method of claim 34, wherein the second solution is prepared by first dissolving the acid with the second organic solvent and then dissolving the insulin in the second organic solvent.

36. The method of claim 30, wherein the weight ratio of the insulin to the polymer in the feed solution is larger than about 5:95.

37. The method of claim 20, wherein the weight ratio of the insulin to the polymer in the feed solution is in a range of from about 5:95 to about 50:50.

38. The method of claim 20, wherein both of the first organic solvent and the second organic solvent are substantially soluble in the compressed anti-solvent fluid.

39. The method of claim 20, wherein the compressed anti-solvent fluid, during the contacting step, is at a reduced pressure of larger than about 0.5 relative to the critical pressure of the anti-solvent fluid.

40. The method of claim 39, wherein the compressed anti-solvent fluid, during the contacting step, is at a reduced temperature of larger than about 0.95 relative to the critical temperature of the anti-solvent fluid.

41. The method of claim 40, wherein the compressed anti-solvent fluid, during the contacting step, is at a reduced pressure of larger than about 0.8 relative to the critical pressure of the anti-solvent fluid.

42. The method of claim 20, wherein the compressed anti-solvent fluid, during the contacting step, is in a supercritical state.

43. The method of claim 20, wherein the compressed anti-solvent fluid comprises compressed carbon dioxide.

44. The method of claim 20, wherein the compressed anti-solvent fluid consists essentially of only compressed carbon dioxide.

45. The method of claim 20, wherein during the contacting step, the feed solution is introduced into a flowing stream of the compressed anti-solvent fluid, the direction of flow of the feed solution, when introduced into the flowing stream of the compressed anti-solvent fluid, is at an angle of from about 45° to about 180° relative to the direction of flow of the compressed anti-solvent fluid.

46. The method of claim 20, wherein the contacting step is conducted under conditions so that the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 50 percent.

47. The method of claim 20, wherein the contacting step is conducted under conditions so that the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 70 percent.

48. The method of claim 19, wherein the biocompatible polymer includes a poly(lactic acid).

49. A particulate product, comprising multi-component particles including insulin and a biocompatible polymer, the multi-component particles having a primary particle mass median diameter of smaller than about 5 microns and having a degree of insulin encapsulation of larger than about 30 percent.

50. The particulate product of claim 49, wherein the degree of insulin encapsulation is larger than about 50 percent.

51. The particulate product of claim 49, wherein the degree of insulin encapsulation is larger than about 70 percent.

52. The particulate product of claim 49, wherein the degree of insulin encapsulation is larger than about 80 percent.

53. The particulate product of claim 49, wherein the multi-component particles have a primary particle mass median diameter of smaller than about 4 microns.

54. The particulate product of claim 49, wherein the multi-component particles include a weight ratio of the insulin to the biocompatible polymer of larger than about 5:95.

55. The particulate product of claim 49, wherein the multi-component particles include a weight ratio of the insulin to the biocompatible polymer in a range of from about 5:95 to about 50:50.

56. The particulate product of claim 49, wherein the particulate product comprises at least one powder batch containing a unit dose of insulin, the powder batch being contained in a receptacle operable with an inhaler capable of aerosolizing at least a

portion of the powder batch from the receptacle to produce an aerosol including dispersed insulin-containing particles suspended in a carrier gas.

57. The particulate product of claim 56, wherein the powder batch includes the multi-component particles in admixture with a particulate bulking agent.

58. The particulate product of claim 57, wherein the bulking agent comprises lactose.

59. The particulate product of claim 56, wherein the receptacle comprises a plurality of containers, each containing one said powder batch containing a unit dose of insulin.

60. The particulate product of claim 56, wherein the particulate product is in the form of a substantially dry powder.

61. The particulate product of claim 49, wherein the multi-component particles are dispersed in a propellant fluid and contained within an inhaler capable of being actuated to permit the propellant fluid to expand to produce single dose aerosol when the inhaler is actuated.

62. The particulate product of claim 49, wherein the multi-component particles have a tap density of smaller than about 0.3 grams per cubic centimeter.

63. The particulate product of claim 49, wherein the biocompatible polymer comprises poly(lactic acid).

64. The particulate product of claim 49, wherein the multi-component particles are substantially in the form of aggregates of the primary particles, wherein the aggregates have a mass average envelope diameter of larger than about 25 microns.

65. A method for generating an aerosol for pulmonary delivery of insulin comprising aerosolization of the particulate product of claim 49 to produce an aerosol including dispersed insulin-containing particles in a carrier gas.

66. A method for generating an aerosol for pulmonary delivery of insulin comprising aerosolization of the particulate product of claim 64 to produce an aerosol including dispersed insulin-containing particles in a carrier gas.

67. The method of claim 66, wherein at least a portion of the aggregates are broken up during the aerosolization so that the aerosol comprises dispersed insulin-containing particles having a mass median aerodynamic diameter of smaller than about 5 microns.

68. The method of claim 67, wherein the dispersed insulin-containing particles have a mass median aerodynamic diameter of from about 1 micron to about 5 microns.

69. A device for generating an aerosol including insulin for pulmonary delivery, comprising:

an inhaler containing a particulate material including insulin, the inhaler being actuatable to aerosolize at least a portion of the particulate material to generate an aerosol including dispersed insulin-containing particles inhalable by a subject for pulmonary delivery of the insulin to the subject;

wherein the particulate material includes multi-component particles including the insulin and a biocompatible polymer and having a degree of encapsulation of the insulin of larger than about 30%.

70. The device of claim 69, wherein the multi-phase particles are substantially in dry powder form.

71. The device of claim 69, wherein the multi-phase particles are suspended in a propellant fluid in a liquid state in the inhaler, which propellant fluid vaporizes during the aerosolization.

72. The device of claim 69, wherein the multi-phase particles have a degree of encapsulation of the insulin of larger than about 50%.

73. The device of claim 69, wherein the multi-phase particles are in the form of aggregates of primary particles, the aggregates having a mass average envelope diameter of larger than about 25 microns and the primary particles having a mass median diameter of smaller than about 5 microns.

74. The device of claim 73, wherein the dispersed insulin-containing particles in the aerosol have a mass median aerodynamic diameter of smaller than about 5 microns.

75. The device of claim 73, wherein the dispersed insulin-containing particles in the aerosol have a mass median diameter of from about 1 micron to about 5 microns.

76. The device of claim 73, wherein, when the inhaler is actuated, at least a portion of the aggregates are broken up to form the dispersed insulin-containing particles in the aerosol.

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